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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,424	07/23/2003	Tiecheng A. Qiao	85504D-W	9183

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EXAMINER
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HYUN, PAUL SANG HWA

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/625,424	QIAO ET AL.	
	Examiner	Art Unit	
	Paul S. Hyun	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### **REMARKS**

In response to a restriction requirement, Applicants withdrew claims 18 and 19. Applicants also amended claims 1, 2 and 4. It should be noted that the amendments have changed the scope of claims 1-17.

With respect to the objection to the Specification cited in the first Office Action, the objection has been withdrawn in light of the corrections made to the Specification.

With respect to the objection to claim 2 cited in the first Office Action, the objection has been withdrawn in light of the amendment made to the claim.

With respect to the rejection of claim 8 under 35 U.S.C. 112 2<sup>nd</sup> paragraph cited in the first Office Action, the rejection has been withdrawn in light of the clarification provided by Applicants.

The replacement drawings submitted by Applicants have been acknowledged.

### ***Claim Objections***

Claim 1 is objected to because of the following informalities:

The limitation "color" recited in line 4 of the claim should be changed to "colorant". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 7-12, 14-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Chee et al. (US 6,429,027 B1).

Chee et al. disclose a two-dimensional array of microspheres randomly immobilized in wells of a substrate (see Figs. 1A, 1B and line 2, col. 5), wherein the concentration of the microspheres can range from a single microsphere to 2 billion microspheres per cm<sup>2</sup> (see lines 1-33, col. 6). The size of the microspheres can range between 0.2 to 200 microns (see lines 33-40, col. 9). The microspheres bear biological probes in the form of a bioactive agent (i.e. nucleic acids [see claim 12]) that binds an analyte of interest (see claim 1). The microspheres can comprise a dye in the form of chromophores that can be developed to produce a unique optical signature that allows one to visually identify the microspheres and the bioactive agent bound to the microspheres (see claim 5 and line 25, col. 21). Chromophores as defined by the Specification absorb light and convert the absorbed light into heat, which is a photo initiated process (see lines 8-10, col. 2).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chee et al. in view of Zuk et al. (US 4,256,834).

Chee et al. disclose the microarray recited in claim 6 except that the reference does not disclose that the optical signature is developed by the means recited in the claim.

Zuk et al. disclose an immunoassay comprising the use of a chemiluminescer that undergoes an enzyme catalyzed redox reaction to produce a detectable signal (see 1-13 col. 20). It would have been obvious to utilize a chemiluminescer disclosed by Zuk et al. as the optical signature means for the microspheres disclosed by Chee et al. The use of such chemiluminescers would be beneficial in assays in which the assay conditions favor chemiluminescence over fluorescence.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chee et al. in view of Wang (US 4,663,277).

Chee et al. disclose the microarray of claim 13 except for the recital of the immobilization of the microspheres by a gelation process.

Wang discloses an immunoassay for a virus accomplished by utilizing microspheres coated with antiviral antibodies. The reference discloses that the method of the immunoassay involves immobilizing the microspheres by placing the microspheres in a gel (see lines 46-50 col. 9).

It would have been obvious to one of ordinary skill in the art to further immobilize the microspheres disclosed by Chee et al. by means of a gel as taught by Wang so that

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the microspheres disclosed by Chee et al. are better secured within the wells of the substrate.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Walt et al. (US 6,023,540) disclose a two-dimensional array of microspheres immobilized in wells disposed at the end of an optical fiber. The microspheres comprise biological probes in the form of functional groups, and a plurality of dyes in varying ratios that define an optical signature for each type of microsphere and analyte. The dyes display a change in its optical signature once an analyte exclusively interacts with the functional groups disposed on the surface of the microspheres, which enables one to identify the microsphere and the analyte.

### ***Response to Arguments***

Despite the amendments made to the claims, the rejections are maintained because the disclosure of the references cited in the first Office Action are still applicable to the claims.

It should be noted that contrary to Applicants' argument (see line 7, page 11), the Specification does not define the limitation "latent" as "colorless". Lines 7-15, page 12 of the Specification discloses that "It is **preferable** that a latent colorant is colorless". According to the disclosure, "a latent colorant" **can** be colored. Therefore, the term "latent" recited in the claims will be interpreted to mean that the distinct color that forms the optical signature is dormant until it is developed, not colorless.

Applicants' argument that there is no likelihood of success of combining the Chee et al. and the Zuk et al. references because the Zuk et al. reference relates to the analysis of a single analyte and the Chee et al. reference relates to the analysis of multiple analytes, has been fully considered but they are not persuasive. The Chee et al. reference discloses that the microspheres can comprise the same bioactive agent for targeting a specific analyte (see lines 29-30, col. 6).

Applicants' argument that the purpose of the gelatin disclosed by the Wang reference is to avoid agglutination, not to immobilize microspheres on a support, has been fully considered, but they are not persuasive. First of all, lines 48-49, column 9 of the Wang reference clearly discloses that the purpose of the gel is to immobilize the microspheres. Secondly, it is the Examiner's interpretation of the reference that **sonicating the gel** and the **storage of the gel in a high  $\mu$  shield** disclosed in lines 54-58 prevents **agglutination of the gel**. The section of the reference describing the agglutination does not appear to describe the role of the gel with respect to the microspheres.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul S. Hyun whose telephone number is (571)-272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PSH  
06/19/06

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